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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,394	11/10/2000	Show-Mean Wu	70788.01	5370

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05/28/2003

Scimed Life Systems Inc
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EXAMINER

NOLAN, SANDRA M

ART UNIT

PAPER NUMBER

1772

8

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/710,394	Applicant(s) WU, SHOW-MEAN	
	Examiner Sandra M. Nolan	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

1. Pursuant to entry of any amendment in the response dated 24 February 2003 (Paper No. 6), claims 1-21 are pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 21 April 2003 (Paper No. 7) was considered by the examiner.

Rejections Withdrawn

3. The 35 USC 112 rejection of claims 3, 4, 7, 8, 12, 15, 18, and 21, as set out in section 3 of the 26 September 2002 office action (Paper No. 5), is withdrawn in view of applicant's amendments and arguments in Paper No. 6.
4. The 35 USC 103 rejection of claims 1-21 over Fugoso et al (US 5,964,778), as set out in section 6 of Paper No. 5, is withdrawn in view of applicant's arguments in Paper No. 6.

New Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe the chemical nature of the urethane polymers employed in making the catheter balloon material claimed. The mere recitation of trademarks/tradenames, without a definite description of the polymers referred to by those names, is not a sufficient disclosure. See MPEP 608.01(v).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (US 5,814,705).

Ward teaches the production of catheters (col.1, lines 24-25) from block copolymers produced so that it has tailored glass transition temperatures ("GTT") (col. 8, lines 34-62). The block copolymer may be made from urethane blocks (claim 3 of the patent at col. 14, lines 53-59).

Ward fails to teach the specific GTT ranges claimed of the specific amounts of urethanes used to make its block copolymers.

In the absence of convincing objective evidence to the contrary, it would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ suitable amounts of the urethane block to make block copolymers having the GTT's recited in the claims.

It is well known in the polymer art that block copolymers are made by combining preformed polymer blocks, so that the blend of claims 1-15 is made during the preparation of Ward's block copolymers.

The motivation to employ the block copolymers of Ward to make catheters is found at col. 1, lines 24-50, where compositions having good shape-memory are said to be used in biomedical devices.

It is deemed desirable to make catheters from compositions having good shape-memory in order to enhance insertion but not irritate the blood vessels during use.

10. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 6,284,856).

Lee teaches catheters (col. 3, line 64) made from compositions containing two copolymers, one with a GTT of -50 to 10 degrees C and a second one with a GTT of 12 to 65 degrees C (col. 8, lines 5-13). The two copolymers are derived from urethane oligomers (col. 3, lines 23-24 and col. 7, lines 9-11).

Oligomers are known in the polymer art to be polymers, so that the urethane oligomers are polyurethanes.

Lee fails to teach the specific amounts of each copolymer that applicant claims.

In the absence of convincing objective evidence to the contrary, it would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the urethane oligomers of Lee to make polymers for use, in suitable amounts, in copolymer blends from which catheters are made.

The motivation to employ the urethane oligomers of Lee in its copolymers and blends is found at col. 7, lines 9-12 of Lee, where the use of urethane oligomers is said to produce a matte finish, which prevents blocking.

It is deemed desirable to prevent blocking when making catheters in order to simplify the manufacturing process.

Response to Arguments

11. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication should be directed to the Examiner, Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/305-5436. The fax number for after final communications is 703/872-9310. The receptionist answers 703/308-0661.



S. M. Nolan
Patent Examiner
Technology Center 1700

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26 May 2003